

# **Mortara ECG Warehouse Annual Support**

## **Statement of Work**

### **Scope of Work**

#### **I. Maintenance of www.ecgwarehouse.com website**

Maintenance of content and upload forms including remote hosting of web server and response to inquiries at [info@ecgwarehouse.com](mailto:info@ecgwarehouse.com). Updating of "Request Upload for FDA Access" pages as needed.

#### **II. Validation and import of ECG studies**

Establish contact with Sponsor organization via Upload Request at [www.ecgwarehouse.com](http://www.ecgwarehouse.com) site; creation of secure folder for upload from Sponsor or Central Lab to ECG Warehouse; validation of annotated ECGs; feedback regarding syntax errors as needed; import of datasets into ECG Warehouse; notification to FDA that dataset is ready for review.

#### **III. Application support for ECG Warehouse client**

Process support inquiries for use of ECG Warehouse client application. Support inquiries handled by Mortara customer service representatives.

#### **IV. System support subsidy for web and database servers**

Subsidy for hosted web and database servers with redundant, fault tolerant design. Prescribed back-up and archiving activities. Expansion of disk array storage capacity as dictated by ECG Warehouse growth.

#### **V. On-Site training for FDA reviewers**

On-site training for one or more FDA reviewers. Costs include travel and lodging for Mortara trainer.

#### **VI. Export of blinded datasets upon request by FDA.**

Export of sponsor, compound, lab and subject blinded ECG data to support research mission of Cardiac Safety Research Consortium.

#### **VII. ECG Warehouse quarterly volume reporting to FDA**

Quarterly reporting on volume of annotated ECGs and annotated ECG studies in ECG Warehouse. Additional customized reporting provided upon request.

### **VIII. Engineering support subsidy for application development**

Engineering support subsidy for new development and application enhancement based upon user feedback.

Period of performance: September, 200~~7~~<sub>8</sub> – August, 200~~8~~<sub>9</sub>

## **Mortara ECG Warehouse Annual Support**

<b>DELIVERABLES</b>		<b>COST</b>
I.	Maintenance of <u>www.ecgwarehouse.com</u> website	\$
II.	Validation and import ECG studies (\$/study)	\$
III.	Application support for ECG Warehouse client	\$
IV.	System support subsidy for web and database servers	\$
V.	On-site training for FDA reviewers (\$/session)	\$
VI.	Export of blinded datasets upon request by FDA	\$
VII.	ECG Warehouse quarterly volume reporting to FDA	\$
VIII.	Engineering support subsidy for application development	\$

**BUSINESS/PRICING PROPOSAL**

**Mortara ECG Warehouse: September, 200<sup>8</sup>~~x~~ TO August, 200<sup>9</sup>~~x~~**

Cost Breakdown:	Deliverables	\$ -
	Total Contract	\$